REMARKS

Claims 1, 4-9, 12, 13, 15-20, 22, 25-28, 129, 135-142 and 144-146 were previously pending in this application (as per the May 26, 2010 Office Action). Applicant attempted to cancel these claims and introduce claims 147-166 into the application in the response dated November 23, 2010. That response however was considered non-responsive according to the Action dated February 1, 2011 because according to the Examiner it presented only claims drawn to a non-elected invention. Applicant then filed another response on August 1, 2011 in which it was argued that the restriction between the previously pending claims and the newly introduced claims was improper. That response was also considered non-responsive by the Examiner, citing MPEP 821.03. That section of the MPEP states that responses considered non-responsive by the Examiner should not be entered. Accordingly, Applicant believes that claims 1, 4-9, 12, 13, 15-20, 22, 25-28, 129, 135-142 and 144-146 are still pending in this application and presents such claims in this response. Applicant also presents claims 147-166 in this response. As a result, claims 1, 4-9, 12, 13, 15-20, 22, 25-28, 129, 135-142 and 144-166 are pending.

Restriction Requirement

Applicant previously traversed the restriction between claims 147-166 and the previously pending claims. (Response dated August 1, 2011.) These reasons are reiterated below.

First, the Examiner mischaracterized the elected invention, and in doing so incorrectly concluded that new claims 147-166 are not readable on the elected invention. The restriction requirement dated January 30, 2001 set forth twelve different inventions (Groups I-XII). In response, Applicant elected Group I (original claims 1-28) drawn to "a combination immunization method of employing an oligonucleotide and an antigen for inducing an (sic) mucosal immunity in a subject, wherein the oligonucleotide sequence has the following formula: 5' X1X2GCX3X4 3' wherein C and G are unmethylated, wherein X1, X2, X3x and X4 are nucleotides, and wherein the antigen is not encoded in a nucleic acid vector." (Page 2 of the Restriction Requirement.)

Claim 1, as pending at that time, recited

"A method for inducing a mucosal immune response, comprising: administering to a mucosal surface of a subject an effective amount for inducing a mucosal immune response of an oligonucleotide, having a sequence including at least the following formula:

5' X1 X2CGX3 X4 3'

wherein C and G are unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and exposing the subject to an antigen to induce the mucosal immune response, and wherein the antigen is not encoded in a nucleic acid vector."

Moreover, claim 1 as pending prior to the reply filed on November 23, 2010 recited

"A method for inducing a mucosal immune response, comprising:

administering to a subject in need of a mucosal immune response an effective amount for inducing a mucosal immune response of an oligonucleotide 8 to 100 nucleotides in length, having a sequence including at least the following formula:

5' X1X2CGX3X4 3'

wherein C is unmethylated, wherein X1, X2, X3, and X4 are nucleotides, and an antigen,

wherein the antigen is not encoded in a nucleic acid vector, the oligonucleotide and the antigen are both administered vaginally, rectally, intranasally, ocularly, or by inhalation to the subject, a cytokine and an immune stimulating complex are not administered to the subject, and the antigen is not a Streptococcus pneumoniae antigen."

There is no recitation of a boosting limitation in the description of Group I, nor in claim 1 as it was pending at the time of the restriction, nor in claim 1 as it was last pending. Also, none of these recited that antigen could not be administered before or after mucosal administration of antigen and oligonucleotide.

Moreover, none of the other Groups in the restriction requirement recites a boosting limitation, nor is any of these other Groups restricted to a particular order of administration of the antigen and the oligonucleotide.

Accordingly, there is nothing in the record that supports the Examiner's characterization of the elected invention. The elected invention is as stated in the restriction, and new claim 147-166 are readable thereon.

Second, the Examiner has not met her burden regarding restriction between new claims 147-166 and the previously pending claims. In particular, as set forth in MPEP 803(I), in order for restriction between two inventions to be proper, the Examiner must establish that there would be a serious burden if restriction were not required. The Examiner not asserted that a serious

burden would exist and has not provided any evidence of such burden as required by MPEP 808 ("Every requirement to restrict has two aspects: ... (B) the reasons why there would be a serious burden on the examiner if restriction is not required ... "). More specifically, the Examiner has not shown by appropriate explanation a separate classification between the new and previously pending claims, a separate status in the art when they are classifiable together, or a different field of search. MPEP 808.02. In the absence of showing of even one of these requirements, there is no reason to divide independent or related inventions. Id.

Applicant requests reconsideration under 37 C.F.R. 1.143 and/or that such restriction be made final so that Applicant may proceed with a petition under 37 C.F.R. 1.144.

Outstanding Rejections

Notwithstanding the foregoing, Applicant provides herewith a response to the rejections asserted in the May 26, 2010 Action.

Double Patenting Rejections

Claims 1, 5-9, 12, 15-18, 22, 129, 135-137 and 139-142 are provisionally rejected as being unpatentable over claims 1, 4, 5, 9-11, 13 and 14 of copending application No. 10/300,247. As stated previously, Applicant notes the provisional rejection but defers substantive rebuttal until the cited application is allowed. MPEP 804(I)(B) states that "the merits of such a provisional rejection *can* be addressed by both the applicant and the examiner without waiting for the first patent to issue" (emphasis added). Notably, the MPEP does not require that the merits *must* be addressed in such a situation. Moreover, the MPEP also states that "the 'provisional' double patent rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that 'provisional' double patenting rejection is the only rejection remaining ...". Id. At that point, the examiner must withdraw the provisional rejection and allow the claims. Consistent with this practice, Applicant defers substantive rebuttal of the provisional rejections until the cited co-pending application is allowed.

Claims 1, 4-9, 12, 13, 15-20, 22, 25-28, 129, 135-142 and 144-146 are rejected on the grounds of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 7,488,490, in view of U.S. Patent No. 6,689,757.

Applicant has rebutted this rejection previously and the Examiner is directed to the prior responses including that dated April 9, 2010. In response to Applicant's most recent rebuttal, the Examiner states the rejection is proper "so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure." (May 26, 2010 Action, page 8.) Applicant respectfully points out that the Examiner has not made any showing that the induction of a mucosal immune response following mucosal administration of a CpG oligonucleotide was *known* in the art at the time the instantly claimed invention was made. This information could be gleaned only from the instant application. Accordingly, even by the Examiner's own standards, the rejection and its reliance on hindsight is improper.

In addition, the Examiner further states that "the ['049] patent claims do not have to specifically recite a mucosal immune response; such would naturally flow from using the method recited in the patent claims." (May 26, 2010 Action, page 8.) Applicant respectfully traverses. The Examiner has made no showing that a mucosal immune response would "naturally flow" from the methods of the '490 claims. Such claims do not recite mucosal immune response induction or mucosal administration of a CpG oligonucleotide, and nor do they necessarily require mucosal administration of the CpG oligonucleotide. Accordingly, a mucosal immune response would not "naturally flow" from the methods of the '490 claims.

One of ordinary skill in the art would have no knowledge, and similarly would have had no reasonable expectation, that a mucosal immune response could be induced upon mucosal administration of a CpG oligonucleotide based on the teachings of the '490 and the '757 patents. Such teaching is provided only in the instant application.

For at least these reasons, reconsideration and withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. §103

Claims 1, 4-9, 12, 13, 15-20, 22, 25-28, 129, 135-142 and 144-146 are rejected under 35 U.S.C. §103(a) as being unpatentable over Krieg et al. (US 6,239,116) in view of each Agrawal et al. (US 6, 426,334), Briles et al. (US 6,042,838), Craig (US 6,689,757), and Kincy-Cain et al. (Infect. Immun., 1996, 64:1437-1440).

Applicant has rebutted this rejection previously and the Examiner is directed to the prior responses including that dated April 9, 2010. In response to Applicant's most recent rebuttal, the Examiner maintains the obviousness rejection based on presumed inherent teachings in the cited art. As argued previously, an obviousness rejection cannot be based on that which is unknown at the time of the invention. In re Rijckaert, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). An obviousness rejection requires that "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. 103(a). One of ordinary skill in the art at the time the invention was made had no knowledge of the ability of a CpG oligonucleotide to induce mucosal immunity when administered to a mucosal site. The instant application is the first disclosure of this ability of CpG oligonucleotides. The instant claims therefore could not be obvious to one of ordinary skill in the art at the time of the invention because it was not known, nor could it have been reasonably expected, prior to the invention that CpG oligonucleotides could induce mucosal immunity. In relying upon inherency, the Examiner is using knowledge gleaned from the instant disclosure, and this too is improper.

For at least these reasons, reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicants' representative at the telephone number indicated below to discuss any outstanding issues relating to the allowability of the application.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. C1040.70006US00.

Respectfully submitted,

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